

BAck iN the Game: A Smartphone Application to Support Athletes Returning to Sport After Serious Injury (BANG)

NCT03959215

Trial Informed Consent Form

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Back in the Game Trial: CONSENT FORM

Linköping University, Institution for Medicine and Health in collaboration with Linköping Orthopaedic Clinic, Capio Artro Clinic, Stockholm, Capio Lundby, Gothenburg is conducting a study about returning to sport after surgery to the anterior cruciate ligament (ACL). The aim of the study is to investigate whether using the Back in the Game smartphone application can facilitate returning to sport after ACL surgery.

The app has questions and other material to support you in returning to your sport. If you accept to participate in the study, you will either receive a little bit of material, or a lot of material. You will be given instructions about how to download the app, and log in details to access the material. You will then receive push notifications about once per week for six months with instructions about what to do.

You will also receive some questions about participating in sport and physical activity for two years after surgery. We will examine your knee function with, among other things, tests for muscle strength, at 1 year after your knee surgery.

Once we have collected the data, the results will be summarised and you will receive a short report of the main study results. The report will not contain individual results.

Participating in the study is voluntary, and you can stop participating whenever you wish without having to give a reason. Participating in the study does not affect your treatment in any way.

All people working on this research project have a responsibility to maintain confidentiality of all individual data. All data we collect are coded. All data in the app are encrypted and stored on Linköping University's server. Data are handled in accordance with the General Data Protection Regulations, GDPR (EU 2016/679), and you have the right to know what information is collected about you, request correction if there are errors, or request restriction/deletion of data.

The Data Protection Ombudsman can be reached at dataskyddsbud@regionostergotland.se. If you wish to file a complaint regarding the processing of your personal data, you can contact the Data Inspectorate, which is the supervising authority responsible for data protection.

Collected material may be used, in de-identified form, in other studies that have received ethical approval.

The study is approved by the Regional Ethics Review Board in Linköping. If you have questions or concerns during the study period, you can contact Professor Joanna Kvist, physiotherapist, Linköping University, joanna.kvist@liu.se, 013 284-664.

I accept to participate in this research study on returning to sport after ACL surgery. I have received verbal and written information about the study, and I understand that information. Any questions I had about the study have been answered.

Date:

Place:

Name:

Social security number:

Signature: